REMARKS

The application has been amended and is believed to be in condition for allowance.

This amendment is being filed as part of an RCE application.

The invention provides a tubular element 2 serving to support an end of a section of a prosthesis in order to enable a realization of a connection between a prosthesis 10 and an end section 12 of a blood vessel 11. The tubular element is stiff as disclosed by the original description and claims. Note that the tubular element must be stiff in order to allow the suture to be pulled tight on the portion of the tubular element comprised between the two ends 2a and 2b.

Claim 1 has been amended to remove the recitation giving rise to the rejection under section 112, 1st paragraph. Withdrawal of this rejection is therefore solicited.

Claim 14 is new.

Claims 1-4 were rejected as anticipated by GRUDEM et al. 6,511,491.

Claims 1-4 were rejected as anticipated by KLESHINSKI 5,755,778.

Claim 11 is rejected as anticipated by GOLDEN 2004/0050393.

Claims 1 and 11 are rejected as anticipated by SAKURA, Jr. 4,214,587.

Claims 5-9 were rejected as obvious over GRUDEM et al. in view of KILLION et al. 6,159,238.

Claims 10, 12, and 13 are rejected as obvious over SAKURA, Jr. in view of JP 06,319,755.

Claim 1 has been amended to clarify that the device of the invention is not a stent or prosthesis, but is exclusively a tubular connecting element which creates a joint between a prosthetic element and a blood vessel (aorta). Claim 14 details this structure.

Support for this amendment can be found in Figures 2-5 and the specification, at least page 4:

"As shown in figure 2, a prosthesis 10 is passed into the tubular element 2 and is externally folded over the first end 2a. The segment of prosthesis which has been folded over the first end 2a is fastened on the proximal slender elements 3, so that the slender elements 3 penetrate completely in and through the wall of the prosthesis 10, exiting therefrom by the free ends 3a thereof. As the prosthesis 10 used is not circumferentially elastic, on being folded outwardly it might ruffle and bend; to avoid this eventuality the folded tract of prosthesis 10 can be slit in a longitudinal direction in order to give a minimum level of circumferential deformability to the prosthesis 10. Alternatively a segment of the prosthesis 10 could be connected to the tubular element 2 in the above-described way, in which the tract to be folded over the tubular element 2 exhibits an

increased diameter which is calculated to suit the deformation it will undergo. The prosthetic segment thus exhibits an end which is folded externally over the tubular element 2 and a free end projecting from the tubular element 2 which is connected to a normal aortic prosthesis."

None of the references teach a connecting element being used in combination with a prosthesis. Accordingly, none of these references are anticipatory nor render obvious the present invention.

The original claim has been amended so as to clarify that the device being recited is not itself a stent but rather is a connecting element which creates a joint between a prosthetic element and a blood vessel.

The tubular connecting element is element 2 and the prosthetic element is element 10. The blood vessel is element 11 (Figures 4-5).

As illustrated, the tubular connecting element 2 of the invention goes over the prosthetic element 10. The prosthetic element 10 is then folded over one end of the connecting element 2, thereafter the blood vessel is inserted over this end and a suture applied so that both the prosthetic element and the blood vessel are punctured by the protruding slender elements. See especially Figure 5 in this regard.

None of the references teach or suggest such a combination.

With reference to claims 1-4, GRUDEM teaches a stent device (10), having an annular structure which is not structurally equivalent to the applicant's device, which is a tubular element constituted by a sort of connecting ring which serves to anchor and connect a tubular prosthesis 10 to the neck 12 of an artery (aorta) 11. In other words, the invention is a connector which has the essential task of enabling a realization of a rapid and effective joint between the tubular prosthesis 10 and the aorta 11 neck section 12. It therefore is completely unlike a stent device. It is rather obvious that the structure of the stent of GRUDEM is absolutely incapable of performing such a function (because it is totally different and is constituted by a wall made of netting). The stent of GRUDEM can only be inserted internally of a blood vessel and is in no way structured to conjoin a tubular prosthesis to a vessel.

KLESHINSKI shows a device for anastomasis provided with barbs (74) or a bi-adhesive layer (26) for adhering to the internal walls of the tracts of vessel to be conjoined. It is important to note, however, that the device of KLESHINSKI is in itself a prosthesis provided with means for hooking to the sections of the vessels it is to connect. What is more, the prosthesis is expandable and therefore deformable, and in order to be positioned must be expanded or dilated exactly like a stent. Substantially, the device of KLESHINSKI, though a device for anastomasis provided with barbs (20), structurally is totally

unlike an annular element such as that of the applicant's invention, which is rigid and serves to support an end of section of a prosthesis in order to enable a realization of a connection between a prosthesis 10 and an end section 12 of a blood vessel 11. The annular element is structured only for realizing the connection with the modalities that are described and illustrated in the accompanying figures, which involve a tobacco-pouch final suture. This type of structure is possible only where there exists a support constituted by the annular element which is the object of the applicant's application, which enables the suturing to be done. A suture done in this way is entirely impossible with the device of KLESHINSKI, which is deformable. The only similarity is constituted by the barbs (20) which in any case are very different from the slender elements 3 of the applicant, which are very small in order completely to cross the width of the prosthesis 10 and exit at their ends. In KLESHINKI it would be intolerable for the barbs (20) to be so conformed and of such a size to perforate the vessel walls they interact with.

Thus, neither reference is structurally equivalent to that recited. GRUDEM teaches a stent 10, having an annular structure which is not structurally equivalent to the present invention. Likewise, KLESHINSKI, though a device provided with barbs, is structurally dissimilar to the recited invention. Note that as claimed, the recited invention is rigid and serves to support an end of a section of a prosthesis in order to enable a

realization of a connection between the prosthesis and an end section of the blood vessel. Again, see Figure 5. The invention's annular element is structured for realizing a connection with the modalities that are described and illustrated in the application's drawing figures.

Neither of the references anticipates such a structure, or combination of elements.

Claim 11 is not anticipated by GOLDEN 2004/0050393.

The anastomosis system shown by GOLDEN is very complicated and is very different from applicant's device. GOLDEN does not show any **stiff** tubular element for carrying out the connection between the prosthesis (10) and the *neck of the section* (12) *upstream of the removed part of the aorta* by a very simple large-step in-and-out suture which can be performed only by using the stiffness of the tubular element (2) and without a plurality of discrete fasteners.

Claims 1 and 11 are not anticipated by SAKURA, Jr. Nor are claims 10, 12, and 13 obvious over SAKURA, Jr. in view of JP 06,319,755.

The device shown by SAKURA, except for the *outwardly extending barbs*, is totally different from applicant's device because:

SAKURA is a radially resilient **spring**, i.e. elastically deformable;

does not comprise a prosthesis but only a radially resilient **spring** with *outwardly extending barbs* which has only the function of connecting the ends of two vessels;

the junction is performed only by the *outwardly extending barbs* (see Figs. 8 and 9) and the elastic deformability of the spring (10); and

said spring (10) can be used only for small vessels.

Claims 5-9 are not obvious over GRUDEM et al. in view of KILLION. KILLION does not cure the defects of the independent claim. These claims are also allowable at least for depending from an allowable independent claim.

In view of the above, reconsideration and allowance of all the pending claims are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

Roland E. Long, Jr., Reg. No. 41,949
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

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